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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,810	11/12/2003	Robert S. Davidson	57778.8004.US00	6949
34055	7590	10/05/2007		
PERKINS COIE LLP POST OFFICE BOX 1208 SEATTLE, WA 98111-1208			EXAMINER VU, JAKE MINH	
			ART UNIT 1618	PAPER NUMBER
			MAIL DATE 10/05/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/706,810	DAVIDSON ET AL.	
	Examiner	Art Unit	
	Jake M. Vu	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-83 is/are pending in the application.
- 4a) Of the above claim(s) 2 and 50-83 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of Applicant's Restriction Response filed on 08/06/2007; Information Disclosure Statements filed on 05/24/2007, 04/09/2007, 04/11/2006, 11/17/2005, 05/13/2005, and 02/28/2005.

- Claims 1-83 are pending in the instant application.
- Claims 2, and 50-83 are withdrawn from consideration.

Election/Restrictions

Applicant's election of Group I (claims 1, 3-49) and specie elections of "cough curing agents, carrageenan, stearic acid, carboxymethylcellulose, lipid, starch and pullulan" in the reply filed on 08/06/2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Priority

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. US 60/426598, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. A coating on at least one of the said outer surface or powder matrix was never disclosed in the provisional application. Thus, the pending claims do not have benefit of an effective filing date of 11/14/2002.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3 and 28 are rejected under 35 U.S. 102(e) as being anticipated by BARKALOW et al (US 2004/0096569)

Applicant's claims are directed to a composition comprising of: a film layers; a coating on at least one outer surface comprising a cough-curing agent, such as menthol.

BARKALOW teaches a composition comprised of: multiple film layers, such as two layers (see [0092]) which would read on a film layer and a coating on at least one outer surface, since the coating would be an additional layer. Additional disclosures include: a cough-curing agent, such as menthol (see [0028]); and powder coating (see [0065]).

Claims 1, 3-7, 16, 17, 20-32, 36-39, 42-45 are rejected under 35 U.S.C. 102(b) as being anticipated by BROWN et al (WO 98/20863; which is also published as US 6,783,768).

BROWN teaches a composition comprised of: a film layer (see US 6,783,768 at col. 8, line 50); a coating (see col. 8, line 47-50) on at least one outer surface comprise a medicant, such as diltiazem (see col. 11, line 6). Additional disclosures include: coating material in the form of powder material (see col. 3, line 38), which reads on powder matrix; medicant can be in any layer (see col. 55-63); mucosa adherent, such as hydroxypropyl cellulose (see col. 11, line 52-53); bulking agent, such as xylitol (see col. 11, line 4); thickness less than 1mm (see col. 8, line 25-28); Eudragit RS (see col. 11, line 51), which is an acrylic acid copolymer; flow agents, Aerosil 200 (see col. 11, line 56).

Note, the film layer dissolving time of is an inherent characteristic of the ingredient. Since the prior art's film layer is the same ingredient as claimed by Applicant, it would be reasonable to assume the dissolving would be the same.

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Note, it is inherent that the powder material has less than 10% water since BROWN's starting materials are dry powder.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 3-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over BROWN et al (WO 98/20863; which is also published as US 6,783,768) in view of BARKALOW et al (US 2004/0096569).

Applicant's claims are directed to a composition comprising of: a film layer comprising of pullulan; a coating, comprising of carrageenan, stearic acid, carboxymethylcellulose, lipid, starch; medicant, which is a cough curing agent, such as menthol; sweetener; talc; and an acrylic copolymer.

As discussed above, BROWN teaches a composition comprised of: a film layer (see US 6,783,768 at col. 8, line 50); a coating (see col. 8, line 47-50) on at least one outer surface comprise a medicant, such as diltiazem (see col. 11, line 6). Additional disclosures include: coating material in the form of powder material (see col. 3, line 38), which reads on powder matrix; medicant can be in any layer (see col. 55-63); mucosa adherent, such as hydroxypropyl cellulose (see col. 11, line 52-53); bulking agent, such

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as xylitol (see col. 11, line 4); thickness less than 1mm (see col. 8, line 25-28); Eudragit RS (see col. 11, line 51), which is an acrylic acid copolymer; flow agents, Aerosil 200 (see col. 11, line 56); powder coating has the advantage of reduction in waste and improved coating efficiency (see col. 2, line 41-44).

BROWN does not teach using pullulan; carrageenan; stearic acid; carboxymethylcellulose; lipid; starch; medicant, which is a cough curing agent, such as menthol; sweetener; and talc.

As discussed above, BARKALOW teaches a composition comprised of: multiple film layers, such as two layers (see [0092]) which would read on a film layer and a coating on at least one outer surface, since the coating would be an additional layer. Additional disclosure includes: a cough-curing agent, such as menthol (see [0028]); powder coating (see [0065]); pullulan (see [0042]); carrageenan (see [0024]); stearic acid (see [0089]), which is a lipid; carboxymethylcellulose (see [0024]); starch (see [0087]); sweetener (see [0097]); talc (see [0088]); and acrylic copolymer (see [0087]). These are common ingredients in the art of edible film (see Applicant's provisional application 60/426598).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate pullulan, carrageenan, stearic acid; carboxymethylcellulose, starch, menthol, sweetener, and talc into BROWN's composition. The person of ordinary skill in the art would have been motivated to make those modifications, because these are commonly used ingredients in the art of edible film and BARKALOW suggested powder coating can be used [see 0065]), and

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reasonably would have expected success because both references are in the same filed on endeavor.


Telephonic Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jake M. Vu whose telephone number is (571) 272-8148. The examiner can normally be reached on Mon-Tue and Thu-Fri 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jake M. Vu, PharmD, JD
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MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER